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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,303	01/20/2004	Barry Lenard Reed	025217-0122	7169
22428	7590	02/28/2007	EXAMINER	
FOLEY AND LARDNER LLP			GEORGE, KONATA M	
SUITE 500			ART UNIT	PAPER NUMBER
3000 K STREET NW			1616	
WASHINGTON, DC 20007				
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE		DELIVERY MODE	
3 MONTHS	02/28/2007		PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/759,303	REED ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 December 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 36-44 and 46-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 36-44 and 46-60 is/are rejected.
- 7) Claim(s) 61-65 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 20 January 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date: _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/28/06</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 36-44 and 46-65 are pending in this application.

#### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on November 28, 2006 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

#### ***Action Summary***

2. The rejection of claims 36-44 and 46-55 under 35 U.S.C. 103(a) over Sunshine et al. in view of Knight et al. is being maintained for the reasons stated in the previous office action.
3. Applicant acknowledges the addition of claims 56-60. These claims are being rejected under the 35 U.S.C. 103(a) of the previous office action.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 36-44 and 46-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. (US 5,100,918) in view of Knight et al. (US 3,306,252).

Applicants claims an apparatus for applying a physiologically active agent to the dermal surface comprising a container and in said container an non-occlusive percutaneous or non-occlusive transdermal drug delivery system that comprises a therapeutically effective physiologically active agent, a dermal penetration enhancer and a volatile liquid to act as a vehicle.

***Determination of the scope and content of the prior art***

**(MPEP §2141.01)**

Sunshine et al. teach in column 10, lines 33-40 a topical composition comprising S(+) ibuprofen in an amount sufficient to prevent or treat ultraviolet radiation-induced erythema (0.5 to 10 wt%). The composition can contain suitable solvents or vehicles including ethanol, etc. (col. 9, lines 35-38). The topical composition can be combined with other types of sun-protective and/or anti-erythema topical agents such as sunscreens containing PABA ester (col. 10, line 49 through col. 11, line 10). Column 10, lines 1-20 teach topical ingredients that are present in commercial sunscreens such as preservatives and oils.

Knight et al. discloses a shielded aerosol medicament dispenser for applying a medicament to a specific part of the body. The device comprises a vessel having a pressure chamber containing the fluid under pressure, a valve member and a hood mounted in a fixed axial position (col. 1, lines 36-52). It can be concluded from figure 1, that the nozzle of the device is placed perpendicular to the dermal surface. Examiner interprets the hood of Knight to be equivalent to the shroud of the instant invention.

Applicants' describes the shroud on page 45, [0227] to "...envelope[s] the spray, providing an effective closed system, which deposits the active agent into the skin...". The hood portion of the device of Knight delivers the active agent in the same manner as claimed by applicant (see Fig. 1).

***Ascertainment of the difference between the prior art and the claims***

**(MPEP §2141.02)**

Sunshine et al. does not teach a container for the composition or that the delivery system provides metered doses and contains a shroud.

***Finding of prima facie obviousness***

***Rational and Motivation (MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Knight et al. (devices for the delivery of the composition an aerosol medicament dispenser) with the composition of Sunshine et al. (composition comprising an active agent and a sunscreen) to teach the claimed invention of a container comprising an active agent and a sunscreen and a container for the composition. With respect to the system providing meter doses, it is the position of the examiner that when the pumps of the aerosol and non-aerosol devices are depressed, the device delivers a metered dose of the composition to the patient.

***Response to Arguments***

5. Applicant's arguments filed December 4, 2006 have been fully considered but they are not persuasive.

Applicants argue that the composition of Sunshine et al. does not become dry to the touch within three minutes of application to the skin. It is the position of the examiner that "dry to the touch within three minutes of application to the skin" is functional language and does not carry patentable weight. If the composition of Sunshine et al. is the same as what is claimed, it is presumed to have the same function. It is argued that Sunshine et al. does not teach a composition comprising a "penetration enhancer". While the composition of Sunshine et al. does not explicitly teach a "penetration enhancer", applicants' specification teaches that para-aminobenzoate compounds can be used as "penetration enhancers". Sunshine et al. disclose a composition comprising a physiologically active agent, a para-aminobenzoate compound and a volatile liquid, which reads on the claimed composition. Applicant relies on a Declaration filed in application 09/125,436 now US Patent 6,299,900, to teach that Sunshine et al. does not teach the claimed composition. The declaration submitted by applicant is not persuasive. Applicant compares the composition of EP 522 405 with the composition of the instant invention. Upon review of EP 522 405, the examiner notices that it is directed towards "Composite Ophthalmic Lenses", which is unrelated to the present invention. The relevance of the declaration is therefore not understood.

***Allowable Subject Matter***

6. Claims 61-65 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach the composition comprising the physiologically active agent as claimed.

***Conclusion***

7. Claims 36-44 and 46-60 are rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

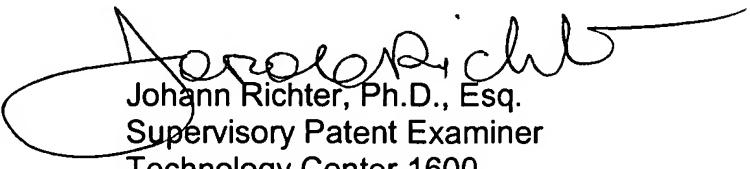
***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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